

REMARKS**1. Restriction Requirement**

The Examiner has required a restriction between the claims of Groups I – IV as outlined on page 2 of the Office Action. This requirement is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner has urged that the inventions listed in Groups I –IV do not relate to a single general inventive concept under PCT Rule 13, because they lack the same or corresponding special technical feature.

The Examiner will first of all note that no unity of invention objection was raised during the international phase of this application, which also applies the unity of invention standard of PCT Rule 13. An international application which complies with those unity of invention requirements must then be accepted by all the designated and elected offices, including the USPTO, since Article 27 (1) of the Patent Cooperation Treaty does not permit any national law or national office to require compliance with different regulations relating to the contents of the international application. Thus, the U.S. application must be examined for unity of invention consistent with the Patent Cooperation Treaty, not just by giving verbal assent to the unity of invention standard. Rather, the USPTO must actually apply that standard. See *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D.Va. 1986).

In support of an argument that the claims of the groups identified by the Examiner do not share a common technical feature, the Examiner refers to the Blaszczyk-Thurin et al. publication. But that publication does not support the Examiner's position. The Blaszczyk-Thurin et al. publication describes a murine monoclonal antibody BR55-2 which is directed to the Lewis Y antigen. The publication also mentions that the antibody BR55-2 can mediate cytotoxicity and inhibit tumor growth in nude mice (p. 447, right column, middle of 2<sup>nd</sup> paragraph). However, there is no data or support that the antibody can be used to treat tumor cells in a cancer patient. Such a short statement without any evidence can not be considered as enabling. In particular, in

the treatment of cancer patients further factors like specificity, efficacy and adverse effects based on e.g. low specificity for tumor cells have to be considered. This document provides in length a study of the binding interactions of specific amino acid residues of the antibody with particular functional groups of the Lewis Y structure. From this document it can not be concluded that the antibody has a sufficient specificity for tumor cells since it is explicitly stated that “these differences in reactivity clearly suggest that Y reactive antibodies recognize different epitopes. This differential specificity might also be extended to interaction with both tumor and normal cell” (p. 450, right column, 2<sup>nd</sup> half of 4<sup>th</sup> paragraph).

For the above reasons, it is submitted that the Examiner’s restriction requirement is improper, should be withdrawn, and all of the claims should be examined in this single application. However, in order to be fully responsive, Applicants elect, with traverse, the claims of group II, that is claims directed to a method of treatment. Claims 3-16 and 19-21 have been amended to depend upon method of treatment claim 2, and claims 27 and 28 have been added as also directed to the method of treatment. Thus, the claims of group II should properly be claims 2-16, 19-21 and 27-28.

## **2. Election of Species**

In addition to the restriction requirement, the Examiner has also required an election of species, more specifically a three part species election. This requirement is respectfully traversed. Reconsideration and withdrawal thereof are requested. Applicants submit that this election of species requirement is unnecessarily detailed requiring the Applicants to elect aspects related to optional features of the invention, when such elections are not required to provide the Examiner with sufficient focus for purposes of an initial search and examination. In particular, while it may be appropriate to request the Applicants to elect a specific aberrant glycosylation protein, Applicants submit that it is not appropriate to require the election of a single kind of monoclonal antibody nor to elect whether the antibody is administered in combination with a carrier or with labeling.

However, in order to be fully responsive to the requirement, Applicants elect, a humanized antibody directed to Lewis Y which is administered together with a carrier.

Favorable action and early allowance of all the claims in view of the above are requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of \$450.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson, Registration No 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

- Attached is a Petition for Extension of Time.
- Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,



By \_\_\_\_\_

Leonard R. Svensson  
Registration No.: 30,330  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
12770 High Bluff Drive, Suite 260  
San Diego, California 92130  
(858) 792-8855  
Attorney for Applicant